REMARKS

Claims 1, 3-19, 22-27 and 29-31 are in the case. Claims 1, 3-5, 7 and 29 are currently amended. Claims 3-19, 22-27, 30 and 31 were previously presented. Claims 2, 20, 21 and 28 are cancelled, without prejudice.

The Examiner has objected to claims 1 and 29 due to minor informalities. These informalities have been corrected.

The Examiner has rejected claim 1, and a number of the claims dependent thereon, under 35 USC §102(b) as being anticipated by Lalor et al. GB 2,164,277.

Lalor et al. '277 describes the design of bone drill, which, as stated in the first paragraph (page 1, lines 5 to 7), is of a type developed in 1964. To the best of Applicant's knowledge, this size/type of bone drill is no longer in regular use for taking biopsies. The huge (almost industrial size) samples harvested with this type of device are not considered necessary for diagnosis, although large diameter devices of similar type may still sometimes be employed for harvesting bone for grafting to another part of the body (Declaration By the Inventor, paragraph 5). Furthermore, although the Lalor et al. '277 bone drill has an appearance that is superficially similar to that of the claimed biopsy needle, the bone drill is considerably larger, and it has a very different function. As a result, there are significant differences in structure and operation between the bone drill of Lalor et al. '277 and Applicant's biopsy needle.

In particular, the outer diameter of the shank 10 of the bone drill of Lalor et al. '277 is approximately 10 mm, and the grooves 13 are approximately 25 mm in length, about 2 mm in width and above 1 mm in depth (page 1, lines 72 to 75). By means of this construction, the bone drill of Lalor et al. '277 is intended to greatly reduce contamination of tissue surrounding the sample by bone dust dislodged during drilling (page 1, lines 35 to 40), and for this purpose, the grooves are relatively wide and deep, with apertures 14 at the proximal (upstream) ends to cause bone dust formed by the action of the teeth 12 to pass along the grooves and through the apertures 14 into the tubular shank (page 1, lines 76 to 89).

In contrast, the slots in Applicant's biopsy needle device have a much different purpose, which is not taught nor suggested by the bone-dust-conveying slots and apertures of Lalor et al. '277. Namely, in Applicant's biopsy needle, the slots are constructed for abrasion of material surrounding the tip of the biopsy needle to facilitate lateral movement of the needle within the bone cavity, thus facilitating detachment of the sample within from the remainder of the tissue. As a result, the slots of Applicant's biopsy needle are much narrower, e.g., having a width of less than 1 mm (claim 1, as amended, and page 11, last paragraph), and shallower than those described by Lalor et al. '277 (Declaration By the Inventor, paragraphs 7 and 8).

We submit that Applicant's invention, as now more clearly claimed, is not taught, nor suggested, by Lalor et al. '277, whether taken alone or in proper combination with any other reference. Applicant therefore respectfully requests that the rejection under 35 U.S.C. §102 be withdrawn in view of the amendments herein and the above remarks.

Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 13533-002001.

Respectfully submitted,

Date: Aug 18, 2004

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Attorney's Docket No.: 13533-002001 / F/USP81213

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Paul Laurence Cervi
Serial No. : 09/955,790
Filed : September 19, 2001
Title : BIOPSY NEEDLE

Art Unit : 3736
Examiner : Brian Scott Szmal

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION BY THE INVENTOR

I, Paul Laurence Cervi, hereby declare that:

1. I am the sole inventor for the above-identified patent application.

2. My credentials and experience in the field of Biopsy Needles are as follows:

I qualified as a physician (MB, University of Dublin) in 1984, and during my undergraduate career undertook a Bachelor of Science (BSc) degree in 1981. I became a member of the Royal College of Physicians in Ireland in 1986. I became a member and subsequently a fellow of the Royal College of Pathologists, UK, in 1994. I was appointed consultant haematologist in 1996. As a haematology specialist for the past 15 years, I regularly perform bone marrow biopsy procedures. I started designing improved bone marrow biopsy needles in 1998, and have subsequently also designed an improved lymph node biopsy device (the subject of a separate U.S. patent application.) I have a strong research interest and have 17 publications in peer reviewed journals.

3. I have studied the most recent Examiner's action issued for this patent application, along with the cited prior art and the pending claims.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

August 18, 2004
Date of Deposit

Signature

Timothy A. French
Typed or Printed Name of Person Signing Certificate

4. The Examiner has rejected claim 1, and a number of the claims dependent thereon, under 35 USC §102(b) as being anticipated by Lalor et al. GB 2,164,277. I respectfully contest this rejection.

5. Referring first to the device described by Lalor et al., this is a design of bone drill, which, as stated in the first paragraph (page 1, lines 5 to 7), is of a type developed in 1964. To the best of my knowledge, this size/type of bone drill is no longer in regular use for taking biopsies. The huge (almost industrial size) samples harvested with this type of device are not considered necessary for diagnosis. (I believe, however, that large diameter devices of similar type may still sometimes be used for harvesting bone or grafting to another part of the body.)

6. Although the Lalor et al. bone drill has a superficially similar appearance to the biopsy needle of my invention, the bone drill is considerably larger, and has a very different function. As a result, there are significant difference in structure and function between the bone drill of Lalor et al. and my biopsy needle. In particular, the outer diameter of the shank 10 of the bone drill of Lalor et al. is approximately 10 mm, and the grooves 13 are approximately 25 mm in length, about 2 mm in width and above 1 mm in depth (page 1, lines 72 to 75). By means of this construction the bone drill of Lalor et al. is intended to greatly reduce contamination of tissue surrounding the sample by bone dust dislodged during drilling (page 1, lines 35 to 40), and for this purpose the grooves are relatively wide and deep and have apertures 14 at their proximal ends to cause bone dust formed by the action of the teeth 12 to pass along the grooves and through the apertures 14 into the tubular shank (page 1, lines 76 to 89).

7. In contrast, the slots in my biopsy needles have a very different purpose. Namely, in my biopsy needle the slots are constructed for abrasion of material surrounding the tip of the biopsy needle to facilitate lateral movement of the needle within the bone cavity, thus facilitating detachment of the sample from within the remainder of the tissue. As a result, the slots of my biopsy needle are much narrower, e.g., having a width of less than 1 mm (claim 1, as amended, and page 11, last paragraph), and shallower than those described by Lalor et al..

I hereby declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: 14th August 2004

D. Paul Cervi.

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